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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/761,143	01/16/2001	Muraleedharan G. Nair	MSU 4.1-541	4327

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EXAMINER	
LEITH, PATRICIA A	

ART UNIT	PAPER NUMBER
1655	

DATE MAILED: 12/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/761,143	NAIR ET AL.	
	Examiner	Art Unit	
	Patricia Leith	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3 and 5-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3, and 5-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 11/16/06 has been entered.

Claims 1, 3 and 5-25 are pending in the application and were examined on their merits.

The Affidavit filed under 37 CFR 1.132 by Inventor Mulareedharan Nair with the RCE on 11/16/06 has been fully considered. The Affidavit is sufficient to overcome the previous rejection under 35 USC 112 first paragraph Written Description.

Applicant's remarks filed 11/16/06 are moot in light of the removal of the previous rejection under 35 USC 112 first paragraph Written Description.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-15, 18, 27-29 and 30 are rejected under 35 U.S.C. 102(b) based upon a public use or sale of the invention.

Claims 1, 4-15, 18, 27-29 and 30 are directed toward inhibiting cyclooxygenase/prostaglandin H synthase via 'providing' a mixture comprising cyanidin and anthocyanins. Tart and sweet cherries inherently have these phytochemicals in light of Applicant's Affidavit filed on 11/16/06 as well as in the Instant specification. Therefore, these claims are directed toward eating sweet and tart cherries (fresh or dried). It is well known that tart and sweet cherries have been eaten in this country for centuries. Inhibition of cyclooxygenase/inflammation would have merely been an inherent consequence of eating cherries.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3 and 5-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gryglewski et al. (1987) in view of Lietti et al. (GB 1,589,294).

Gryglewski et al. (1987) studied the anti-inflammatory mechanism of 3-cyanidol (cyanidin) *inter alia* and discovered that cyanidin inhibits cyclooxygenase (see entire reference, especially pp. 318 – 319 and Table 10). It is noted that cyclooxygenase is a synonym for prostaglandin H synthase/synthetase.

Gryglewski et al. did not specifically teach administration of anthocyanins *and* cyanidin for treatment of inflammation/inhibition of cyclooxygenase.

Lietti et al. (GB 1,589,294) disclosed that anthocyanidins, and specifically cyanidin possessed anti-inflammatory activities (pp.1, lines 11-33 and especially 'cyanidine' = cyanidin structure). Lietti et al. specifically teaches that "Anthocyanidines are a group of known polyphenolic substances. These products, as well as being preparable by total chemical synthesis, may be obtained by hydrolysis of their glycosides which are widely distributed in nature. these glycosides, and particularly the glucosides, are known as anthocyanins..." (p. 1). Lietti et al. further teach that "Clinically, the substances may be administered singly or in the form of mixtures with one another, in the pure state or in the form of crude or partially purified extracts, for example extracts of the crude product obtained by hydrolysis of naturally-occurring mixtures of anthocyanins. Secondly, Lietti et al. clearly teach that anthocyanins are hydrolyzed to cyanidin (p.1, lines 27-28, in addition to the same teaching in the Instant Specification). Lietti et al. proposed the incorporation of "at least 0.2% and most preferably at least 0.5% by weight of anthocyanidines" but more

concentrated forms)1% to 5%) were preferred (see p. 2, lines 34-39). Lietti et al. further suggest the incorporation of suitable forms for oral administration of the anthocyanidins such as tablets, capsules, solutions and suspensions as well as excipients including vegetable triglycerides, water, glycol, lecithin, buffering agents, thickening agents, wetting agents and emulsifying agents (inter alia) (see p. 2, lines 5-19). . Thus, *in-vivo*, anthocyanins are converted (hydrolyzed) to the non-glycosylated anthocyanidins before entry into the intestinal tract. Consequently, one of ordinary skill in the art would have recognized that cyanidin and the glycosidic forms of cyanidin, would have been virtual pharmaceutical equivalents since anthocyanins essentially degrade in the body to cyanidin.

Therefore, it would have been obvious to administer cyanidin along with anthocyanins a cyanidin-3-glucoside which yield the aglycone structures of cyanidin because it was already known in the art that cyanidin inhibited cyclooxygenase and was therefore an inhibitor of inflammation. It was clear from the prior art, as well as the Instant specification that it is the aglycone structure of anthocyanins; i.e., cyanidin which has the properties of inhibiting inflammation via cyclooxygenase inhibition. One of ordinary skill in the art would have had a reasonable expectation that administration of cyanidin, along with its glycoside (the anthocyanin form) would have provided for additive results in inhibiting inflammation, because it was known in the art at the time the invention was made that the anthocyanins (glycosidic forms) were hydrolyzed to the active aglycone; e.g., cyanidin.

One of ordinary skill in the art would have been motivated to administer a dry cyanidin/anthocyanin mixture in order to administer the composition in tablet form. It was clear from the prior art that anthocyanidins were routinely added to tablets and capsules, and therefore, the purified ingredients would have been beneficially dried in order to mix with dry carrier ingredients.

Although the prior art does not specifically teach the use of dried cherry pulp as a carrier, it is deemed that the form of the composition i.e.; dried or liquid, does not change the overall effect of the active ingredients, nor does it materially change the composition as a whole. For example, the nutritional composition as disclosed by a liquid form of the composition would have performed similarly to a dry composition because the active ingredients were the same. Variations of nutritional forms such as powders, elixirs, beverages, or snack bars would have all been suitable packaging means for the active ingredients of the Instant invention, and would not have required a substantial inventive contribution in order to have created these forms of the composition for ease of administration and/or to enhance the manufacturability of the product (to make the product more appealing to the consumer).

Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 220 F2d 454,456,105 USPQ 233; 235 (CCPA 1955). see MPEP §

2144.05 part II A. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to determine all operable and optimal concentrations of components because concentration of anthocyanidins is an art-recognized result-effective variable as evidenced by Lietti et al. which would have been routinely determined and optimized in the pharmaceutical art. It would be conventional and within the skill of the art to identify the optional concentrations of cyanidin/cyanidin glucoside in order to create compositions containing appropriate cyanidin/cyanidin glycoside for optimizing the antiinflammatory properties of the composition.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on Monday - Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on (571) 272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Patricia Leith
Primary Examiner
Art Unit 1655

December 8, 2006